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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,439	12/11/2003	Jacob Bar-Tana	1567/70937-ZA /JPW/AG	2054

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,439	BAR-TANA, JACOB	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 29-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 29-54 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/915,412.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 29-54 are presented for examination.

Requirement for Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 29-35, drawn to a method for the treatment of syndrome X comprising the oral administration to a human subject an effective amount of a xenobiotic fatty acid compound, classified in class 514, subclass 558, for example, depending on the compound used.

II. Claims 36-41, drawn to a method for the treatment of dyslipoproteinemia comprising the oral administration to a human subject an effective amount of a xenobiotic fatty acid compound, classified in class 514, subclass 558, for example, depending on the compound used.

III. Claims 42-48, drawn to a method for lowering plasma levels of triglycerides in a human subject comprising the oral administration to the subject of an effective amount of a xenobiotic fatty acid compound, classified in class 514, subclass 558, for example, depending on the compound used.

IV. Claims 49-54, drawn to a method for increasing plasma levels of HDL cholesterol comprising the oral administration to a human subject an effective amount of a xenobiotic fatty acid compound, classified in class 514, subclass 558, for example, depending on the compound used.

The inventions are distinct, each from the other, for the following reasons:

Inventions I through IV are patentably distinct. Inventions are patentably distinct if it can

be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, it is noted that the ultimate therapeutic objective of, for example, Invention I (i.e., treating syndrome X in a subject) is distinct from the therapeutic objective of, for example, Invention II (i.e., treating dyslipoproteinemia in a subject), of which each is distinct from the therapeutic objectives of any one or more of Inventions III or IV.

Inventions I through IV are held to be patentably distinct because the treatment of any one of Inventions I through IV would not necessarily result in the treatment of the other invention. The patient populations in which each method would be practiced are distinctly different (e.g., patients requiring the treatment of syndrome X versus patients requiring the treatment of dyslipoproteinemia), such that the treatment of one patient population would not necessarily suggest, anticipate or render obvious the treatment of the other patient population. While there may be incidental overlap in the groups of patients experiencing, for example, syndrome X, and those experiencing, for example, dyslipoproteinemia, the therapeutic objectives, endpoints and steps required to treat such conditions are vastly different and do not reasonably suggest, anticipate or render obvious the treatment of the other.

Furthermore, the dosage amounts or frequency and route of administration necessary to effect the treatment of patients with, for example, syndrome X, would necessarily be independent and distinct from that required for the treatment of patients with, for example, dyslipoproteinemia, due to the differences in etiology of such a condition and the activity of the claimed agent(s) in treating such a condition. Moreover, one skilled in the art could practice the invention of any one or more of inventions I, II, III or IV without practicing the invention of any

one of the other inventions. Thus, Inventions I through IV are properly considered patentably distinct from one another.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups I through IV is not required for any one of the other groups, the inventions are held to be distinct and restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of xenobiotic fatty acid compounds defined by the formula R-COOH, wherein R may be any of the moieties recited in present claim 29, for example.

The species are independent or distinct because the species of xenobiotic fatty acid compounds recited in the present claims are each structurally, functionally and/or chemically distinct from any one other xenobiotic fatty acid compound recited in the present claims such that a comprehensive search of the patent and non-patent literature for any one such compound would not necessarily result in a comprehensive search of any one or more of the other xenobiotic fatty acid compounds recited in the claims. Notwithstanding that Applicant may have established an underlying common function to a combination of this broad genus of compounds, namely, that they are capable of treating syndrome X, dyslipoproteinemia, lowering plasma triglycerides or increasing plasma HDL cholesterol in a human subject, it remains that the art does not necessarily recognize such a shared function as being common to each of the huge number of compounds encompassed by the claims. Despite the fact that there may be incidental overlap between any one or more of the compounds contained within the claims, such does not change the fact that each of the xenobiotic fatty acid compounds encompassed by the claims are distinct from one another because they lack a common physical structure or function and,

therefore, are considered patentably distinct. In addition, the discovery of any one of the presently claimed compounds would not necessarily anticipate or reasonably suggest or render obvious any one or more of the other compounds of the present claims.

Applicant is required under 35 U.S.C. 121 to elect a **SINGLE** disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 29-54 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, the identity of each substituent contained in the generic formula, a structural depiction of the compound and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

A telephone call was made to John P. White at Cooper & Dunham, LLP on Thursday, March 2, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

March 2, 2006

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